UNITED STATES DISTRICT CO	DURT
WESTERN DISTRICT OF NEW	YORK

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DOUGLAS J. HORN and CINDY HARP-HORN,

Plaintiff,

AFFIDAVIT OF

KENNETH D. GRAHAM, Ph.D.

-VS-

Case No. 15-cv-701 FPG/MJR

MEDICAL MARIJUANA, INC., DIXIE HOLDINGS, LLC a/k/a DIXIE ELIXERS RED DICE HOLDINGS, LLC, and DIXIE BOTANICALS,

Defendants,

Kenneth D. Graham, Ph.D. declares the following, pursuant to 28 USC §1746, under penalty of perjury:

- 1. I am a Forensic Toxicologist with over 25 years of experience in the field. I was retained on behalf of the Plaintiffs to evaluate the evidence and testimony involving the tetrahydrocannabinol (THC) content of the Dixie X Elixir Tincture product taken by Plaintiff, and whether the product complies with federal statutes for controlled substances. As such, I am fully familiar with the facts and circumstances set forth in this affidavit.
- 2. I make and submit this affidavit in rebuttal to MMI/RDH's response to plaintiff's opposition to MMI/RDH's motion pursuant to Fed. R. Civ. P. 54(b) for reconsideration and revision of the Court's order denying MMI/RDH's motion for summary judgment, as it relates to the Plaintiffs' RICO claim, on the basis that the alleged descriptive error for the Court to find that Dixie X contained a "resin extract derived from the Cannabis sativa plant" and was thus considered marijuana as defined under the Controlled Substance Act in 2012.

- 3. On April 17, 2019, the Court issued a Decision and Order with respect to various motions between the parties, which granted in part and denied in part MMI/RDH's motion for summary judgment, leaving plaintiff's claims for fraudulent inducement and civil RICO, and dismissing all other claims against the defendants. (Dkt. No. 88).
- 4. As background to the Decision and Order, the Court noted that despite the extraction and distillation process, Dixie X contains a detectable amount of THC, the primary psychoactive constituent of the plant species *Cannabis sativa*. (DKt. No. 88, p. 3).
- 5. The Court acknowledged that a determination of whether Dixie X constituted a controlled substance in 2012 under the federal Controlled Substances Act (CSA) was a "legal issue that is foundational to this litigation" (Dkt. No. 88, p. 7).
- 6. The Court opted to address this foundational legal issue by limiting the focus on a definitional element in one section of the CSA that related specifically to the determination of marijuana in *Cannabis sativa* plant material. *See* 21 U.S.C. § 802(16).
- 7. The defendants erroneously assert that the Court's alternative assessment of whether the *Cannabis sativa* plant material met definitional requirements of a controlled substance under the CSA amounts to a consideration and subsequent rejection by the Court of the plaintiff's argument that, regardless, the Dixie product is a controlled substance because it contains a measurable amount of THC.

8. The defendants erroneously allege that the Court was explicit in its rejection of the plaintiff's argument regarding THC content by stating:

"At the time, the CSA made no distinction on the basis of THC concentration. See *Monson*, 589 F.3d at 961 ('[M]arijuana is defined to include *all* Cannabis sativa L. plants, regardless of THC concentration.'); *N.H. Hemp Council, Inc. v. Marshall*, 203 F.3d 1, 7-8 (1st Cir. 2000)." (Dkt. No. 88, p. 9).

This statement does not represent an explicit rejection of plaintiff's argument regarding THC content in the formulated product since the THC concentration referenced by the Court applies to the content of the plant material and not the final product.

- 9. The defendants erroneously claim that the Court further rejected plaintiff's position by stating "counterintuitively, certain derivatives of the industrial hemp plant were not included in the definition of marijuana—and therefore were not unlawful under the CSA—even if they contained trace amounts of THC.". Again, this statement does not represent an explicit rejection of plaintiff's argument regarding THC content in the formulated product since the THC concentration in certain derivatives of industrial hemp plant material is not at issue in this case.
- 10. The Court did not comment, reject or rule on whether the Dixie product was eligible for an exemption of certain cannabis plant material, and products made therefrom, that contain tetrahydrocannabinols under 21 U.S.C. §1308.35.
- 11. The Court did not comment, reject or rule on the validity of Plaintiff's argument that the Dixie product is primarily a controlled substance because it contains a measurable quantity of THC, which, by definition, renders it a Schedule 1 controlled substance in other sections of the CSA. See 21 U.S.C. §1308.11.

- 12. By claiming that the Court considered and rejected the Plaintiff's argument that the Dixie product was a controlled substance because it contained a measurable concentration of THC, the Defendants are thus asserting that the Court intentionally and willfully contravened other federal statutes under the CSA by rendering its decision based solely on its interpretation of one definitional element under the CSA.
- 13. For assessment of CSA compliance, it is immaterial whether the plant material used to describe the formulation basis of the Dixie product was a resin extract or a non-resin extract. (Dkt. No. 88, p.10). Whether from the resin or other plant material, the extracted CBD and other substances used to formulate and manufacture the product constitutes a "compound, manufacture, salt, derivative, mixture or preparation from such a plant" as defined in the statute. *See* 21 U.S.C. § 802(16).
- 14. Based on the statute, the definition of marijuana contained several potential exceptions. Excluded from the definition of marijuana were certain parts of the plant that are incapable of germination: (1) the mature stalks of the *Cannabis sativa* plant, (2) fiber produced from the stalks of the *Cannabis sativa* plant, (3) oil or cake made from the seeds of the *Cannabis sativa* plant, (4) any compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, fiber, oil, or cake (excluding resin extracts), and (5) the sterilized seed of the Cannabis sativa plant. 21 U.S.C. § 802(16) B(ii).
- 15. In 2012, the formulated Dixie Elixir product contained measurable quantities of tetrahydrocannabinol (THC), the primary psychoactive constituent in marijuana plant material. The presence of THC in the Dixie product was confirmed in certificates of analysis provided by defendant's as well as independent analysis results contracted by Plaintiff.

- 16. The presence of a measurable amount of THC in the Dixie product renders it a Schedule 1 controlled substance as described under 21 U.S.C. §1308.11.
- 17. The Dixie products purchased by the Plaintiff's met the criteria of a controlled substance under several sections of the CSA for the all of following reasons:
 - (i) The Dixie products were derived from processed plant material of the genus *Cannabis sativa* that contains an amount of tetrahydrocannabinol. *See* 21 U.S.C. §802(16).
 - (ii) The Dixie products were formulated using CBD extracted from a portion of a plant (stalks) of the genus Cannabis that would be excluded from the definition of marijuana under the CSA. *See* 21 U.S.C. §802(16).
 - (iii) The Dixie products were formulated, marketed and distributed for human consumption. *See* 21 U.S.C. §1308.35.
 - (iv) The formulated, marketed and distributed Dixie products contained a measurable amount of THC that renders it a Schedule 1 controlled substance as described under 21 U.S.C. §1308.11.
- 18. Upon information and belief, the determination of whether the Dixie X product that plaintiff purchased and allegedly consumed in 2012 met the criteria of a controlled substance under the CSA does not rest exclusively on whether the Court mischaracterized the *Cannabis sativa* plant material extract as a "resin". In the event that the Court agrees with the Defendants that the application of the term "resin" was a true error of the court and their product is not derived from a resin, the Dixie Elixir would still remain a controlled substance by definition under other elements of the CSA since it was derived from an extract, whether mischaracterized as a resin or not, of the *Cannabis sativa* plant (21 U.S.C. §802(16)). , the extract was subsequently formulated, marketed and

distributed for human consumption (21 U.S.C. §1308.35) and the formulated product contained a measurable amount of the Schedule I controlled substance, THC (21 U.S.C. §1308.11).

Dated: October 30, 2019

KENNETH D. GRAHAM, Ph.D.

Subscribed and Sworn to before me this 30 th day of October, 2019.

Notary Public

Commonwealth Of Pennsylvania - Notary Seal
Kelsey Beck-Cullen, Notary Public
Montgomery County
My Commission Expires July 4, 2023
Commission Number 1353768

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